BIOMET SPINE

SEP 20 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	September 6, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 x2214 Fax: 973-257-0232
Trade name:	Nextgen Altius OCT System
Common Name:	Occipito-cervico-thoracic spinal fixation system
Product Code & Classification Name:	KWP - Spinal interlaminal fixation orthosis MNI & MNH – Noncervical, pedicle screw spinal system
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3050 and 888.3070

Device Description:

The Nextgen Altius OCT System is an occipito-cervico-thoracic spinal fixation system. The titanium alloy (Ti-6Al-4V) components in the system includes screws, locking plugs, various types and styles of rods, hooks, lateral connectors, set screws, occipital plates, rod connectors/dominos and various cross connectors. The system also includes CoCr rods fabricated from Co-28Cr-6Mo alloy. Bone screws are placed in the thoracic spine (T1-T3) and hooks are placed in the cervical spine. The rod is inserted and the construct is locked with plugs. Cross connectors can be added to the construct for additional stability.This submission is a line extension to Nextgen Altius OCT System to add alternate styles of occipital plates, occipital screws and occipital locking plugs to the system.

Indications for Use:

When intended for stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput -T3), the Nextgen Altius OCT System is intended for use with allograft or autograft and indicated for: DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); pseudoarthrosis; spinal stenosis; trauma, (i.e., fracture or dislocation); atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumors.

The occipital bone screws are limited to occipital fixation only.

The use of pedicle screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Nextgen Altius OCT System can also be linked to the Biomet Polaris Systems via transitional rods or using Altius Rod Connectors or Polaris Dominoes. Please refer to the individual system's package insert for a list of indications for use for each system.

Summary of Technologies:
The technological characteristics of the new components are the same as, or similar to, the predicate devices in regards to design, indications for use and operational principle.

Performance Data:
Mechanical testing was conducted in accordance with FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004. Per the guidance document, the following testing was conducted: static compression bending, static torsion, torsion fatigue and compression bending fatigue. Testing was conducted in accordance with ASTM F2706, Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model, and an interconnection fatigue test of the plate and rod assembly. The mechanical testing verifies that the subject components are substantially equivalent to other spinal systems currently on the market and has met all mechanical test requirements based on the worst-case construct testing.

Substantial Equivalence:

The subject components in the Nextgen Altius OCT System are substantially equivalent to the current components in the Nextgen Altius OCT System (K113593), the Depuy Mountaineer OCT Spinal System (K042508) and the Vertex Reconstruction Systems (K110522). The Nextgen Altius OCT System is substantially equivalent to these predicate systems with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness.

Conclusion:

The Nextgen Altius OCT System is substantially equivalent to the predicate systems when used as an occipito-cervico-thoracic spinal fixation device. The intended use and fundamental technology of the system remain unchanged. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the other components in the Nextgen Altius OCT System. Based on this information, the subject components do not raise any new issues regarding the safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Spine (aka EBI, LLC)
% Ms. Vivian Kelly MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

SEP 20 2012

Re: K122378
Trade/Device Name: Nextgen Altius OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: September 6, 2012
Received: September 7, 2012

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Nextgen Altius OCT System

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Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122378